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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,323	12/20/2004	Masazumi Nishikawa	263192US0PCT	3573

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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06/25/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/517,323	Applicant(s) NISHIKAWA ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 22, 25-36 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-19, 22, 25-36, and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on February 27, 2009 is acknowledged. Claims 18-19, 22, 25-36, and 39-41 remain under prosecution in this application.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

The rejection of claims 40-41 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants Amendment to the claims to change "composition" to "method", thereby correcting the antecedent basis in the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 18-19, 22, 25-36, and 39-41 under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (US Patent 5,602,183) in view of Norwegian Shark Oil product information sheet has been withdrawn. Applicant's arguments regarding the "topical" administration via oral administration are persuasive. There is no expectation based on the teachings of Martin that an oral administration would serve as a skin protection/wound healing composition.

Newly Applied Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-19, 22, 25-36, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brohuit et al. EP 0321428) in view of Ecomer product information sheet.

Brohuit discloses the use of glycerol ethers in dermatological diseases. The glycerol ethers can be administered orally in the form of capsules and is sold under the TradeName Ecomer (abstract). Ecomer is Shark Liver Oil, see attached product information sheet. The glycerols are present as diesters of fatty acids (column 1, lines 45-48). The capsules contain 0.05g of active substance, thereby meeting the limitation of claim 19. The capsules also contain gelatin and glyercol, which would meet the limitation of claim 31.

Applicant's disclosure on page 8 discloses a method for extracting diacylglycerol ether, triglycerides, and squalene from shark liver oil. Therefore, it is the examiners position that the use of shark liver oil would inherently possess the ether compound, as well as triglycerides and squalene, in the amounts recited in claim 39, and thus the administration of shark liver oil meets the limitations of the instant claims.

Burns caused by intensive sunrays can be partly prevented by administration (column 1, lines 56-58).

Regarding claim 40-41, the claim limitations are considered to be product by process limitations. Since the prior art discloses the same product used for the same

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purpose, the process from which it is made does not hold patentable weight. Applicant's attention is directed to MPEP 2113, which discloses, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Burden is shifted to Applicant to provide a patentable distinction between the administration of the shark liver oils of the prior art and that of the instant claims.

Brohuit does not particularly disclose skin cancer induced by UV light, formation of pigmented spots induced by UV light, formation of freckles induced by UV light, formation of wrinkles induced by UV light, formation of verrucae induced by UV light, and formation of erythema induced by UV light as recited in claims 32-36. Martin additionally does not disclose the daily dosage of the composition.

Regarding the dosages recited in claims 19, 25-26, 30, it is the position of the examiner that one of ordinary skill in this art would have the knowledge for determining optimum dosing schedules of the composition in order to obtain the optimum therapeutic effect of the compound.

Regarding the specific conditions of claims 32-36, it would have been obvious to one of ordinary skill in the art to have used the composition of Brohuit for the treatment of UV light induced skin damage since it is disclosed that the ethers beneficially influence diseases depending upon epidermal growth. Since the prior art discloses the composition can be used to treat UV induced skin damage, it would have been obvious

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to one of ordinary skill in the art to attempt treatment utilizing the composition for the instantly claimed disorders since they all arise from the same origin.

Conclusion

Due to the new grounds of rejection presented in this office action, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615